

**REMARKS****Status of Claims and Request for Rejoinder**

Claims 1-40 were pending in the present application. Claims 7-19 and 28-40 were deemed withdrawn from consideration by the Examiner. By virtue of this response, claims 7-19, 24-27 and 35-40 have been cancelled and claim 1 has been amended. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Claim 1 has been amended to correct an obvious typographical error. No new matter is believed to have been added.

The Examiner has withdrawn claims 28-34 presented as new claims in the response filed by the Applicants on January 27, 2004. Claims 28-34 ultimately depend upon elected claim 1 (which was searched by the Examiner) and therefore incorporate all of the limitations of the claims upon which they depend. The Applicants assert that should the Examiner find claims 1-6 and 20-23 allowable, claims 28-34 should not require additional searching by the Examiner. The Applicants therefore respectfully request rejoinder of claims 28-34 and thank the Examiner for his indication that these claims will be now be rejoined.

**Regarding the Information Disclosure Statements**

The Applicants thank the Examiner for review of the references and return of the initialed PTO-1449 for the Information Disclosure Statements filed by the Applicants on September 9, 2002, January 3, 2003, May 15, 2003 and September 8, 2004.

The Applicants note for the Examiner's convenience that Supplemental Information Disclosure Statements (SIDS) were also filed by the Applicants on April 25, 2005 and herewith. The Applicants respectfully request review of the cited references and return of the initialed PTO SB/08 by the Examiner. Should either of the SIDS or any of the cited references be missing from the file the Applicants are happy to provide copies directly to the Examiner upon request. The Applicants request early notification if any of the cited documents should be missing from the file.

### **Obviousness Type Double Patenting**

Claims 1-6 and 20-23 are provisionally rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 2, 22 and 33 of copending Application No. 09/942,431. The Applicants respectfully traverse this rejection.

The Applicants note, as discussed with Examiner Teller and Supervisory Examiner Campell, in separate conversations, that independent claim 1 (and therefore claims 2-6 and 20-23 and 28-34, which ultimately depend from claim 1) requires that the echinocandin compound recited in the claim be complexed with a carbohydrate. As noted in the present specification, in order to form the complex (which is "a more crystalline form (e.g., a more ordered unit matrix) than the corresponding echinocandin without the carbohydrate." (see *e.g.*, page 2, lines 12-18; page 3, lines 6-8) the echinocandin is recrystallized in the presence of the carbohydrate (*see* page 5-6, bridging paragraph; page 6, lines 15-29; page 24, lines 26-36). As known to those of skill in the art and as described at page 6, lines 15-29, recrystallization requires dissolving the solute (echinocandin) in the solvent and then slowly cooling to form the crystalline solid. In the present application the echinocandin and carbohydrate are dissolved at an elevated temperature and recrystallization results in the complex. This procedure is also described in detail in the Examples at page 24, lines 26-36. Further, claim 1 recites that the carbohydrate so complexed is "released upon dispersion of the echinocandin/carbohydrate complex in water."

In contrast, the claims as allowed in co-pending application USSN 09/942,431 are directed to freeze dried formulations and processes for making and using the freeze dried

formulations. While the claimed formulations and methods include a stabilizing agent which is a carbohydrate, there is no recitation or suggestion of the claimed echinocandin formulation being complexed with the carbohydrate. Preparation of the freeze dried formulations as claimed in USSN 09/942,431 would not result in formation of the presently-claimed complexes, as freeze drying, even in the presence of carbohydrate, is not an equivalent process to recrystallization and would result in amorphous product, not a complex. Indeed, formation of the claimed freeze dried formulations (which require, as is well known to those of skill in the art and as recited in part in allowed claim 40, dissolving the components of the formulation in a solvent(s), freezing with liquid nitrogen, and then sublimating the solvent by applying a vacuum) would, if the presently claimed echinocandin/carbohydrate complex was used as starting material rather than non-complexed echinocandin, result in the destruction of the claimed echinocandin/carbohydrate complex, as the carbohydrate is released upon dispersion in water, as presently claimed, resulting in the echinocandin returning to a more amorphous non-complexed form (see present specification, e.g., page 6, lines 1-14).

In summary, none of the claimed freeze-dried formulations or methods of use recited in the allowed claims of USSN 09/942,431 would contain or suggest the echinocandin/carbohydrate complexes presently claimed and, the claimed processes for preparing these freeze-dried formulations would not result in the formation of the presently claimed echinocandin/carbohydrate complexes nor suggest their preparation. Thus, the Applicants respectfully request withdrawal of the provisional obviousness-type double patenting rejection of claims 1-6 and 20-23.

### **Rejections under §103**

Claims 1-6 and 20-23 are rejected under 35 U.S.C. 103 (a) as allegedly being anticipated by Jamison (USPN 6,323,176). The Applicants respectfully traverse this rejection.

The Applicants note that substituent -OR<sup>5</sup> is described by Jamison et al. with R<sup>5</sup> being a “sugar moiety.” The equivalent position in the present application, R<sup>8</sup> (where R<sup>8</sup> would correspond to the moiety of -OR<sup>5</sup>), is limited in claim 1 to “-OH, -OSO<sub>3</sub>H, -OPO<sub>3</sub>H<sub>2</sub>, -OPO<sub>3</sub>HR<sup>a</sup>, or

-OPO<sub>2</sub>HR<sup>a</sup>, where R<sup>a</sup> is hydroxy, C<sub>1</sub>-C<sub>6</sub> alkyl, C<sub>1</sub>-C<sub>6</sub> alkoxy, phenyl, phenoxy, *p*-halophenyl, *p*-halophenoxy, *p*-nitrophenyl, *p*-nitrophenoxy, benzyl, benzyloxy, *p*-halobenzyl, *p*-halobenzyloxy, *p*-nitrobenzyl, or *p*-nitrobenzyloxy.” Claims 2 and 3 further limit the possible choices for R<sup>8</sup>. None of the recited choices for substituent R<sup>8</sup> in the present application includes a “sugar moiety,” carbohydrate, or sugar moieties of the formulae recited in claim 1 of Jamison et al. In Jamison et al. and the present application -OR<sup>5</sup> and R<sup>8</sup>, respectively, are represented, as would be understood by those of skill in the art, as **covalently bound** substituents, a part of the recited echinocandin molecule.

There is no suggestion in Jamison et al. that -OR<sup>5</sup> should be replaced with the substituents recited for R<sup>8</sup> in the present application and neither is there any suggestion that the echinocandin compounds described in Jamison et al. (where R<sup>5</sup> is a sugar moiety) should be further complexed with a **non-covalently bound** carbohydrate. As would be clearly understood by those of skill in the art, the covalent bonds joining R<sup>5</sup> to the oxygen and the moiety -OR<sup>5</sup> to the echinocandin compound will not be broken by dissolving the echinocandin compounds taught in Jamison et al. in water, and therefore the carbohydrate (R<sup>5</sup>) of Jamison would certainly not be “released upon dispersion of the echinocandin/carbohydrate complex in water,” as recited in pending claim 1.

In view of the above-remarks the Applicants respectfully request withdrawal of the rejection of claims 1-6 and 20-23 over Jamison et al.


**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is earnestly entreated to telephone the undersigned at the number given below prior to issuance of a further action. The Applicants respectfully thank Examiner Teller and Supervisory Examiner Campell for useful discussions related to this application.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **342312003801**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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